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EXAMINER	
NOGUEROLA, ALEXANDER STEPHAN	

ART UNIT	PAPER NUMBER
1753	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/062,313	KARINKA ET AL.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,16 and 18-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *14,16 and 18-27* is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicants' amendment of May 18, 2004 ("the Amendment") does not render the application allowable.

Response to Arguments

2. Applicant's arguments filed May 18, 2004 have been fully considered but they are not persuasive.

Rejections of claims 1-3, 5, 10, 11, and 13 as being anticipated by Park

With respect to the rejection of claims 1-3, 5, 10, and 11, and 13 under 35 U.S.C. § 102(b) as being anticipated by Park, Applicants assert, "The biosensor in Park et al. does **not** disclose the use of an electron mediator in combination with a biosensor employing a working electrode, a reference electrode, and a counter electrode for the determination of the concentration of analytes in a liquid phase (e.g. glucose in blood)" (bottom of page 13 bridging to the top of page 14 of the Amendment). The examiner respectfully disagrees.

As for providing an electron mediator, first, Park clearly discloses using an electron mediator and a motivation for using one. See col. 11, ll. 24-32. Second, although Park refers to NADH as a cofactor and not as an electron mediator, NADH can be construed as an electron mediator because Applicants have defined "redox mediator" to "mean any substance that can oxidize or reduce another molecule, typically an enzyme." See page 7, lines 1-2 of the specification. Park states, "As a result of the experiment, ..., absorption of the ethanol molecules [analyte] into the enzyme immobilized layer **7** generates NADH, which is an electroactive material, by action of the immobilized enzyme. The generated NADH is oxidized into NAD^+ on the working electrode **3** and current flows from the working electrode **3** to the counter electrode **4** at the same time." See col. 8, ll. 41-55 and col. 6, ll. 33-43.

As for using the biosensor to determine the concentration of analytes in a liquid phase, this is an intended use, which Park discloses. Park discloses an embodiment for measuring alcohol concentration in saliva or blood. See col. 11, ll. 15-23.

Rejections of claims 1, 3-7, 10, and 12 as being anticipated by Fujiwara

Applicants state, "Fujiwara et al. does **not** disclose an electrode that functions as a reference electrode" (page 15 of the Amendment). This limitation was addressed in the Office Action of January 21, 2004 ("the Office Action"). Claims 1, 3-7, 10, and 12 are directed to a device. The function of an element in the device, such as an electrode, is an intended use. "The manner in which an apparatus operates is not germane to the issue of patentability of the apparatus itself." *Ex parte Wikdahl* 10 USPQ 2d 1546, 1548 (BPAI 1989); *Ex parte McCullough* 7 USPQ 2d 1889, 1891 (BPAI 198); *In re Finsterwalder* 168 USPQ 530 (CCPA 1971); *In re*

Casey 152 USPQ 235, 238 (CCPA 1967). As stated in the Office Action "a reference electrode can structurally and compositionally be the same as a counter electrode. As described in Applicant's specification, the reference electrode differs from the counter electrode in that current passes through the counter electrodes while the reference electrode is held at a fixed potential and has minimal current passing through; these are solely intended uses." Applicants have not demonstrated how a reference electrode is necessarily compositionally or structurally different from a counter electrode. At least one of the two counter electrodes in Fujiwara is capable of functioning as a reference electrode. Indeed, one with ordinary skill in art at the time of invention would have taken the counter electrodes (5) to be also functioning as reference electrodes since measurements are taken across the measuring electrode and the counter electrodes (col. 3, ll. 25-36); that is, the counter electrodes in Fujiwara are counter/reference electrodes. Furthermore, Applicants disclosure allows for the reference electrode to even comprise reagent and an electron mediator (page 9, lines 25-30 of the specification and claims 4 and 14). This further clouds any distinction as to whether an electrode is a "working electrode," a "counter electrode," and a "reference electrode" other than by specifying how the electrode is actually used, that is, the method in which it is used.

Rejections of claims 1-8 and 10 as being anticipated by Winarta

Applicants state, "Winarta et al. does **not** disclose an electrode that functions as a counter electrode" (page 15 of the Amendment bridging to page 16). This limitation was addressed in the Office Action of January 21, 2004 ("the Office Action"). Claims 1-8 and 10 are directed to a

device. The function of an element in the device, such as an electrode, is an intended use. "The manner in which an apparatus operates is not germane to the issue of patentability of the apparatus itself." *Ex parte Wikdahl* 10 USPQ 2d 1546, 1548 (BPAI 1989); *Ex parte McCullough* 7 USPQ 2d 1889, 1891 (BPAI 198); *In re Finsterwalder* 168 USPQ 530 (CCPA 1971); *In re Casey* 152 USPQ 235, 238 (CCPA 1967). Applicants have not demonstrated how a reference electrode, a counter electrode, and a working electrode are necessarily compositionally or structurally different from one another other than in how they are actually used, the is the method in which they are used. This is especially relevant in regard to Applicants' application because Applicants' disclosure allows for the reference electrode to even comprise reagent and an electron mediator (page 9, lines 25-30 of the specification and claims 4 and 14). If Applicants' reference electrode can be identical to the working electrode in even having the reagent and electron mediator of the working electrode, it is not clear why since Winarta's **R** electrode and **W1** electrode both comprise reagent including an electrode mediator (col. 8, ll. 30-36) these electrodes could not function as either a reference electrode or a counter electrode.

Rejections of claims 1-6 and 9-12 as being anticipated by Forrow

Applicants assert, "Forrow et al. does **not** disclose the use of both an electrode that functions as a counter electrode and a separate electrode that functions as a reference electrode" (page 16 of the Amendment). Applicants further state that the third electrode and fourth electrode of Forrow do not perform the function of a counter electrode or a reference electrode,

but function as a "fill" electrode and as "dummy" electrode, respectively. However, claims 1-6 and 9-12 are directed to a biosensor, which is a device. Whether an electrode is a counter electrode or fill electrode or dummy electrode is, barring a contrary showing, just an intended use or function. Applicants have not demonstrated how a counter electrode is necessarily structurally or compositionally different from a fill electrode or a dummy electrode and why neither the fill electrode nor the dummy electrode of Forrow could not function as a counter electrode. Indeed, Applicants disclosure allows for the reference electrode to even comprise reagent and an electron mediator (page 9, lines 25-30 of the specification and claims 4 and 14). This further clouds any distinction as to whether an electrode is a "working electrode," a "counter electrode," and a "reference electrode" other than by specifying how the electrode is actually used, that is, the method in which it is used.

Status of the Objections and Rejections Applied in the Office Action of January 21, 2004

3. The objection to the drawings is withdrawn.

4. The objection to claim 14 is withdrawn.

5. The rejections under 35 U.S.C. § 112, second paragraph, are withdrawn.

6. The rejections of claims 1-3, 10, 11, and 13 under 35 U.S.C. § 102(b) as being anticipated by Maley are withdrawn.

7. The rejections of claims 1-3, 5, 10, 11, and 13 under 35 U.S.C. § 102(b) as being anticipated by Park are withdrawn.

8. The rejections of claims 1-3, 5, 10, 12, and 13 under 35 U.S.C. § 102(b) as being anticipated by Yee are withdrawn.

9. The rejections of claims 1, 3-7, 10, and 12 under 35 U.S.C. § 102(b) as being anticipated by Fujiwara are withdrawn.

10. The rejections of claims 1-8 and 10 under 35 U.S.C. § 102(e) as being anticipated by Winarta are withdrawn.

11. The rejections of claims 1-6 and 9-12 under 35 U.S.C. § 102(b) as being anticipated by Forrow are withdrawn.

12. The rejections of claims 14-27 under 35 U.S.C. § 102(e) as being anticipated by Feldman are withdrawn.

Claim Rejections - 35 USC § 102

13. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

14. Claims 1-3, 5, 10, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Park et al. (US 5,571,395), hereafter "Park."

Addressing claims 1-3, 5, 10, 11 Park teaches a biosensor strip (abstract) for determining the concentration of an analyte in a sample of biological liquid (col. 11, ll. 15-23) comprising

(a) an electrode support (**1**);

(b) a first electrode disposed on the electrode support, the first electrode being a working electrode (**3**), the working electrode comprising a working ink (col. 6, ll. 56-58) comprising (i) a reagent responsive to the analyte in the sample of the biological liquid (col. 11, ll. 15-32 and claim 4) and (ii) an electron mediator deposited on an electrically conductive material ((**2-1**) and col. 11, ll. 15-32);

(c) a second electrode disposed on the electrode support, the second electrode being a reference electrode (**5**); and

(d) a third electrode disposed on the electrode support, the third electrode being a counter electrode, the counter electrode comprising an electrically conductive material (**4** and col. 6, ll. 56-58).

Note that barring a contrary showing, screen-printed electrode paste or solution is synonymous with electrode ink.

For the requirement of an electron mediator, note that NADH can be construed as a second mediator. Although Park refers to NADH as a cofactor and not as an electron mediator, NADH can be construed as an electron mediator because Applicants have defined "redox mediator" to "mean any substance that can oxidize or reduce another molecule, typically an enzyme." See page 7, lines 1-2 of the specification. Park states, "As a result of the experiment, …, absorption of the ethanol molecules [analyte] into the enzyme immobilized layer **7** generates NADH, which is an electroactive material, by action of the immobilized enzyme. The generated NADH is oxidized into NAD^+ on the working electrode **3** and current flows from the working electrode **3** to the counter electrode **4** at the same time." See col. 8, ll. 41-55 and col. 6, ll. 33-43.

Addressing claim 2, in Park the reference electrode comprises a AgCl "ink" (col. 6, ll. 56-63).

Addressing claim 3, the reference electrode comprises silver (col. 6, ll. 56-62).

Addressing claim 5, the reagent responsive to the analyte in the sample of biological liquid is an enzyme (col. 11, ll. 15-32 and claim 4).

Addressing claim 10, a covering layer (**6**) as claimed is disclosed in Park (Figures 1 and 3).

Addressing claim 11, a mesh (**8**) as claimed is disclosed in Forrow (Figure 1 and col. 7, ll. 5-7).

15. Claims 1, 3-7, 10, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Fujiwara et al. (US 6,309,526 B1), hereafter "Fujiwara."

Addressing claim 1, Fujiwara teaches a biosensor strip (abstract) for determining the concentration of an analyte in a sample of biological liquid (col. 1, ll. 5-12 and col. 3, ll. 20-25), the biosensor strip comprising

(a) an electrode support (**1**);

(b) a first electrode disposed on the electrode support, the first electrode being a working electrode (**4**), the working electrode comprising a working ink comprising (i) a reagent responsive to the analyte in the sample of the biological liquid (col. 3, ll. 14-19) and (ii) an electron mediator deposited on an electrically conductive material (col. 3, ll. 1-2 and col. 3, ll. 14-19);

(c) a second electrode disposed on the electrode support, the second electrode being a reference electrode (**5**); and

(d) a third electrode disposed on the electrode support, the third electrode being a counter electrode, the counter electrode comprising an electrically conductive material (second elecrode **5 and** col. 3, ll. 1-3).

Note that barring a contrary showing, (a) the reagent layer of Fujiwara is synonymous with the working electrode ink, and (b) a reference electrode can be structurally and compositionally the same as a counter electrode. As described in Applicant's specification, the reference electrode differs from the counter electrode in that current passes through the counter electrodes while the reference electrode is held at a fixed potential and has minimal current passing through it. Thus, that an electrode is a "reference electrode" is solely an intended use that does not patentably distinguish the claimed invention from the invention of Fujiwara. Even if both of the "counter electrodes" (5) in Fujiwara do not also function as reference electrodes, that is as counter/reference electrodes, at least one of them is capable of functioning as a reference electrode.

Addressing claim 3, the reference electrode comprises metal (col. 2, ll. 50-55).

Addressing claim 4, the ink on the working electrode is also on the reference electrode (col. 3, ll. 14-15).

Addressing claim 5, the reagent responsive to the analyte in the sample of biological liquid is an enzyme (col. 3, ll. 14-19).

Addressing claim 6, glucose oxidase is disclosed (col. 1, ll. 22-24).

Addressing claim 7, ferricyanide is disclosed (col. 3, ll. 14-20).

Addressing claim 10, a covering layer (**8**) as claimed is disclosed in Fujiwara (Figures 1d and 2).

Addressing claim 12, the counter electrode is positioned relative to the working electrode and the reference electrode such that a liquid sample will contact the working electrode and the reference electrode prior to contacting the counter electrode (as seen from Figures 1d and 2, the sample flow path requires the sample to flow over the electrodes in sequence. If sample is introduced at the flow path end proximate the viewer and proximate electrode **5** is taken to be the "reference" electrode and distal electrode **5** is taken to be the "counter" electrode, then the electrodes are positioned as clamed, since electrode **4** is the working electrode).

16. Claims 1-8 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Winarta et al. (US 6,287,451 B1), hereafter "Winarta".

Addressing claim 1, Winarta teaches a biosensor strip (abstract) for determining the concentration of an analyte in a sample of biological liquid (abstract and col. 14, ll. 20-29), the biosensor strip comprising

(a) an electrode support (**20**);

(b) a first electrode disposed on the electrode support, the first electrode being a working electrode (**W2**), the working electrode comprising a working ink comprising (i) a reagent responsive to the analyte in the sample of the biological liquid (col. 9, ll. 14-42) and (ii) an electron mediator deposited on an electrically conductive material (col. 9, ll. 14-42; col. 9, ln. 66 – col. 10, ln. 6; and col. 10, ll. 49-60);

(c) a second electrode disposed on the electrode support, the second electrode being a reference electrode (**R**); and

(d) a third electrode disposed on the electrode support, the third electrode being a counter electrode, the counter electrode comprising an electrically conductive material (**W1** and col. 9, ln. 66 – col. 10, ln. 6).

Note that barring a contrary showing, (a) the reagent solution for **W2** is synonymous with the working electrode ink, and (b) a reference electrode can structurally and compositionally be the same as a counter electrode. As described in Applicant's specification, the reference electrode differs from the counter electrode in that current passes through the counter electrodes while the reference electrode is held at a fixed potential and has minimal current passing through it; these are solely intended uses.

Addressing claim 2, **W1** comprises the same ink as the reference electrode **R** (col. 10, ll. 41-48).

Addressing claim 3, the reference electrode comprises metal (col. 9, ln. 66 – col. 10, ln. 3).

Addressing claim 4, the reference electrode comprises an ink similar to that used in the working electrode **W2** (col. 8, ll. 43-52).

Addressing claim 5, the reagent responsive to the analyte in the sample of biological liquid is an enzyme (col. 10, ll. 49-58).

Addressing claim 6, glucose oxidase is disclosed (col. 10, ll. 49-58).

Addressing claim 7, ferricyanide is disclosed (col. 10, ll. 49-58).

Addressing claim 8, ferrocene is disclosed (col. 8, ll. 36-40).

Addressing claim 10, a covering layer (**40**) as claimed is disclosed in Winarta (Figure 2).

17. Claims 1-6 and 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Forrow et al. (WO 99/19507), hereafter "Forrow".

Addressing claim 1, Forrow teaches a biosensor strip (abstract) for determining the concentration of an analyte in a sample of biological liquid (preamble of claim 1 and first full paragraph on page 8), comprising

(a) an electrode support (**1**);

(b) a first electrode disposed on the electrode support, the first electrode being a working electrode (**5**), the working electrode (**16**) comprising a working ink comprising (i) a reagent responsive to the analyte in the sample of the biological liquid (page 5, lines 13-15) and (ii) an electron mediator (page 5, lines 27-29 and page 6, lines 8-9) deposited on an electrically conductive material (**4**);

(c) a second electrode disposed on the electrode support, the second electrode being a reference electrode (**6**); and

(d) a third electrode disposed on the electrode support, the third electrode being a counter electrode, the counter electrode comprising an electrically conductive material (**7**).

Also see page 11, ll. 5-22.

Note that barring a contrary showing, although Forrow refers to the third electrode (**7**) as an "indicator" electrode and not as a "counter" electrode these labels are only intended uses that do not necessarily imply a difference in structure or composition. Forrow, for example, teaches that the reference electrode may be identical to the working electrode (page 16, lines 17-19). As discussed in Applicant's specification (page 2), the

purpose of the counter electrode is to balance the oxidation or reduction reaction that occurs at the working electrode.

Addressing claims 2 and 4, Forrow discloses that the reference electrode may comprise reference ink, which is the same as the working ink (page 16, lines 17-26).

Addressing claim 3, several suitable conductive materials for the reference electrode are disclosed (page 22, lines 1-3).

Addressing claim 5, the reagent responsive to the analyte in the sample of biological liquid is an enzyme (Table 1 on page 10).

Addressing claim 6, glucose dehydrogenase is disclosed (*Table 2* on page 18).

Addressing claim 9, phenanthroline quinone and derivatives thereof are disclosed (*Table 2* on page 18 and page 7, lines 1-9).

Addressing claim 10, a covering layer (**15**, **18**, **20**, or **21**) as claimed is disclosed in Forrow (Figure 1).

Addressing claim 11, a mesh (**17** or **19**) as claimed is disclosed in Forrow (Figure 1).

Addressing claim 12, the counter electrode is positioned relative to the working electrode and the reference electrode such that a liquid sample will contact the working electrode and the reference electrode prior to contacting the counter electrode.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

21. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al. (US 5,571,395), hereafter "Park."

Addressing claim 13, Park teaches a method for determining the concentration of an analyte in a sample of biological fluid, the method comprising the steps of

(a) providing the biosensor strip of claim 1 (see the rejection of claim 1, above);

(b) applying the biological fluid to the biosensor strip (implied by Figure 6, which shows test results for various ethyl alcohol concentrations);

(c) inserting the biosensor strip into an analyte monitor (Figure 10);

(d) applying a voltage at the working electrode with respect to the reference electrode (implied by Figure 6, which show current responses for different concentration of ethyl alcohol);

(e) measuring the current flowing between the working electrode and the counter electrode (implied by Figure 6, which show current responses for different concentration of ethyl alcohol); and

(f) correlating the current measured to the concentration of the analyte (Figure 6).

The emphasis in Park is on analyzing gas samples; however it would have been obvious to one with ordinary skill in the art at the time the invention was made to also use the invention of Park to analyze liquid samples because Park discloses a biosensor especially configured for liquid samples (col. 11, ll. 15-32).

22. Claims 1-3, 5, 10, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yee (US 5,672,256), hereafter, "Yee," in view of Park et al. (US 5,571,395), hereafter "Park."

Addressing claim 1, Yee teaches a biosensor strip (abstract) comprising

(a) an electrode support (**1**);

(b) a first electrode disposed on the electrode support, the first electrode being a working electrode (**6a1**, **6a2**, or **6a3**), the working electrode comprising a working ink deposited on an electrically conductive material (col. 4, ll. 63-67);

(c) a second electrode disposed on the electrode support, the second electrode being a reference electrode (**5**); and

(d) a third electrode disposed on the electrode support, the third electrode being a counter electrode, the counter electrode comprising an electrically conductive material (**7** and col. 4, ll. 63-67).

Note that barring a contrary showing, screen-printed electrode paste or solution is synonymous with electrode ink.

Yee does not specifically mention (i) using his biosensor to determine the concentration of an analyte in a sample of biological fluid, and (ii) an electron mediator deposited on the electrically conductive material.

As for using the biosensor to determine the concentration of an analyte in a sample of biological liquid, although the only example disclosed by Yee involves a gas sample (col. 5, ll. 13-20). There is nothing in the patent that suggest that Yee intended his biosensor to be limited to use with gas samples. In fact, liquid sample biosensors are implicitly within the scope of Yee because none of the claims indicates that the biosensor is just for measuring gas samples, "The Background of the Invention" discusses blood sugar measuring apparatuses (col. 1, ll. 33-47), and broad use in the health self-diagnosis/clinical field is disclosed (col. 5, ll. 51-63).

As for providing an electron mediator deposited on electrically conductive material and also using the biosensor to determine the concentration of an analyte in a sample of biological liquid, Park teaches modifying a biosensor for determining the concentration of ethanol in a gas sample so that it can determine the concentration of ethanol in a liquid sample by depositing an electron mediator on electrically conductive material (col. 10, ll. 1-17 and col. 11, ll. 15-32). It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide an electron mediator deposited on electrically conductive material as taught by Park in the invention of Yee because both Yee and Park teach strip-type electrode biosensors having a working ink that includes alcohol dehydrogenase and NADH as cofactor (in Yee see col. 5, ll. 13-25 and in Park see col. 6, ll. 33-43) and as taught by Park the electron mediator will avoid inaccuracies due to electroactive interferants (col. 11, ll. 15-32).

For the requirement of an electron mediator, note that NADH (in Yee col. 5, ll. 14-20) can be construed as a second mediator. NADH can be construed as an electron mediator because Applicants have defined "redox mediator" to "mean any substance that can oxidize or reduce another molecule, typically an enzyme." See page 7, lines 1-2 of the specification. Park, which discusses the activity of NADH in ethanol sensor including alcohol dehydrogenase and NADH in the working ink, states, "As a result of the experiment [measurement], ..., absorption of the ethanol molecules [analyte] into the enzyme immobilized layer **7** generates NADH, which is an electroactive material, by action of the immobilized enzyme. The generated NADH is oxidized into NAD^+ on the working electrode **3** and current flows from the working electrode **3** to the counter electrode **4** at the same time." See col. 8, ll. 41-55 and col. 6, ll. 33-43.

Addressing claim 2, in Yee the reference electrode comprises a carbon "ink" (Yee, col. 4, ll. 63-67).

Addressing claim 3, the reference electrode comprises silver (Yee, col. 4, ll. 59-62).

Addressing claim 5, the reagent responsive to the analyte in the sample of biological liquid is an enzyme (Yee, col. 5, ll. 13-20).

Addressing claim 10, a covering layer (**4**) as claimed is disclosed in Yee (Figures 3 and 4).

Addressing claim 12, the counter electrode is positioned relative to the working electrode and the reference electrode such that a liquid sample will contact the working electrode and the reference electrode prior to contacting the counter electrode (as seen from Figure 3 the working electrode is below the reference electrode and the reference electrode is below the counter electrode. So if sample is introduced at the bottom of the measurement zone define defined by layer **4** when the sample flows to cover the measurement zone it will first contact the working electrode, then the reference electrode and then the counter electrode.).

Addressing claim 13, Yee teaches a method for determining the concentration of an analyte in a sample of biological fluid, the method comprising the steps of

(a) providing the biosensor strip of claim 1 (see the rejection of claim 1, above);

(b) applying the biological fluid to the biosensor strip (implied by Figure 7, which shows test results for various ethyl alcohol concentrations);

(c) inserting the biosensor strip into an analyte monitor (implied by Figure 7, which shows test results for various ethyl alcohol concentrations, together with Figure 3, which shows a connection pad at the bottom of the strip);

(d) applying a voltage at the working electrode with respect to the reference electrode (stated in col. 4, ll. 53-56 and implied by Figure 7, which shows test results for various ethyl alcohol concentrations);

(e) measuring the current flowing between the working electrode and the counter electrode (implied by Figure 7, which shows test results for various ethyl alcohol concentrations); and

(f) correlating the current measured to the concentration of the analyte (Figure 7).

The only example in Yee involves analyzing a gas sample; however it would have been obvious to one with ordinary skill in the art at the time the invention was made to also use the invention of Yee as modified by Park to analyze liquid samples because as discussed in the rejection of claim 1, the scope of the invention of Yee is not limited to gas samples and Yee as modified by Park results in a biosensor especially configured for liquid samples.

Allowable Subject Matter

23. Claims 14, 16, and 18-27 are allowed.

24. The following is a statement of reasons for the indication of allowable subject matter:

a) Claim 14: the nonobvious limitation in the combination of limitations is the requirement that the second electrode have the same reagent as the first electrode. In Winarta the reagent of the second electrode (W1) does not have the enzyme that the reagent of the first electrode (W1) has, which is response to the analyte (col. 8, ll. 43-52);

b) Claims 16 and 18-27 depend directly or indirectly from allowable claim 14.

Final Rejection

25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alex Noguerola
Primary Examiner
AU 1753
July 30, 2004